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Anterior Vertebral Stapling for the Fusionless Correction of Scoliosis.

Changes in motion segment stiffness following staple insertion and measurement of staple loading during movement.

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Introduction

Idiopathic scoliosis is a complex three dimensional spinal deformity for which no absolute etiology has been established. Currently treatment options are limited to observation, bracing, or surgery.

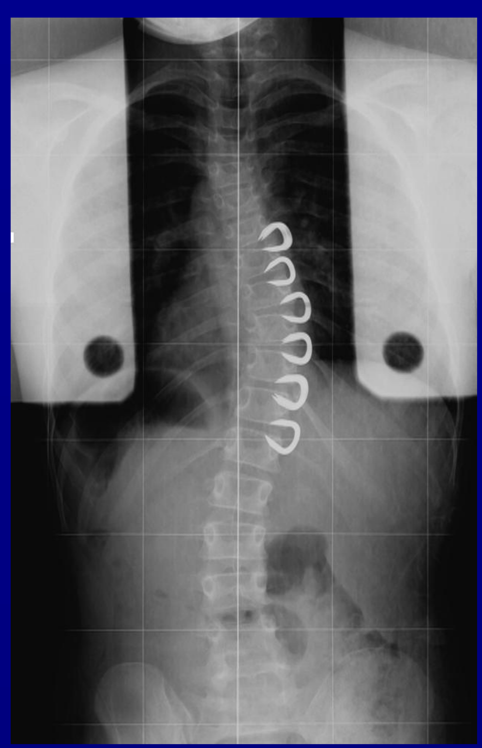
While brace treatment is noninvasive and preserves the growth, motion, and function of the spine, it does not correct deformity and is only modestly successful in preventing curve progression. Conversely surgical treatment with an instrumented spinal arthrodesis usually results in acceptable correction of the deformity however in young patients it is known to have adverse outcomes.

To address the need for effective surgical options in patients who are too young for fusion procedures 'fusionless' growth modulation treatments have been developed. The goal of these techniques is to harness the patient's inherent spinal growth and redirect it to achieve correction, rather than progression, of the deformity. Currently there are several surgical treatments incorporating the fusionless ideology, one of which is anterior vertebral stapling.

Recently clinical interest in stapling has increased following the release of a new staple designed specifically for insertion into the spine by Medtronic Sofamor Danek (Memphis., TN). These staples are manufactured using nitinol, a shape memory alloy (SMA) composed of nickel and titanium. Investigations using large animal models have shown these staples to be effective in modulating vertebral growth [1] and early results from a patient cohort have been promising. [2,3] Despite the increased clinical interest in the use of SMA staples little is known about the mechanism of their effect or the biomechanical consequences of their insertion on the immature spine.

The aims of this study were threefold. Firstly, to measure changes in the bending stiffness of a single spinal motion segment following staple insertion. Secondly, to describe the staple forces that occur with spinal movement. Thirdly, to describe the vertebral structural changes that occur as a consequence of staple insertion.

The shape memory alloy staple



Post-operative radiograph following staple insertion

Materials and Methods

6 to 8 week old bovine thoracic spines were cut into monosegmental functional spinal units consisting of two adjacent vertebrae with intervening disc, facets, and ligaments. The paraspinal muscles and ribs were carefully removed. Three phases of testing were undertaken as described below.

1. Biomechanical Evaluation

A displacement controlled six degree-of-freedom robotic facility was used to test each specimen through a pre-determined range of motion in both un-stapled (control) and stapled conditions. The rotational stiffness of the motion segment for each applied motion was then calculated in Nm/degree of rotation. Paired t-tests were used to compare average stiffness measurements in the stapled and control conditions for each direction of movement ($p<0.05$).

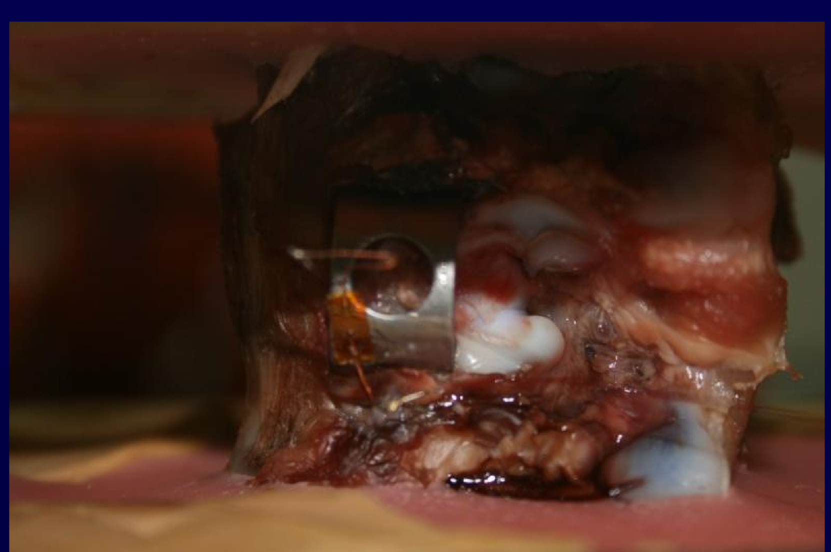
2. Measurement of Staple Loading

Single axis 120Ω strain gauges were attached to the base of the staples in order to measure the strains experienced by the staple during the prescribed motions. The testing protocol used in phase one was repeated and strain data was recorded. A calibration test was then done to convert results into an equivalent staple 'tip' force in Newtons.

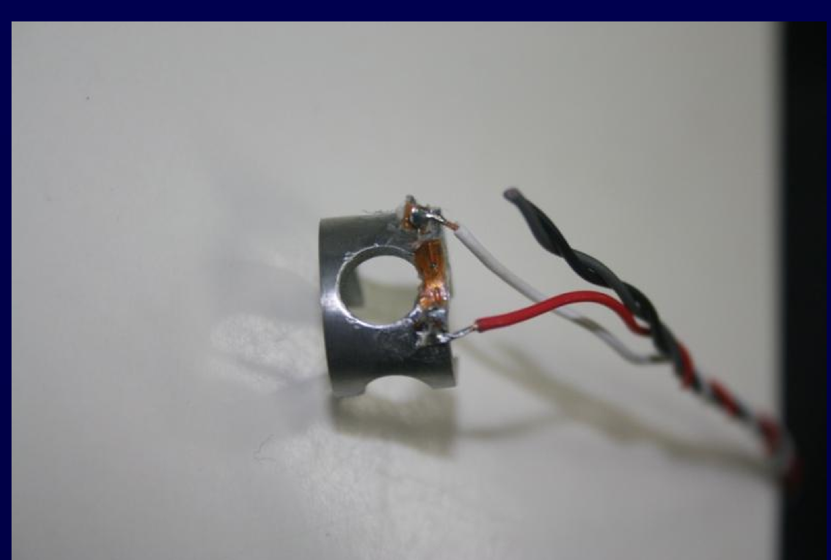
3. Changes in Vertebral Structure Following Staple Insertion

Following completion of the biomechanical tests the staple was removed from the testing specimen using a diamond saw to minimize vertebral damage. The specimen subsequently underwent micro-CT scanning.

The testing robot



Testing specimen following staple insertion



A staple with a strain gauge attached

Results

1. Biomechanical Investigation

The results of the comparison in motion segment bending stiffness between the stapled and non-stapled specimens are presented in the table below.

In the control group where specimens that underwent repeat testing without the insertion of a staple no significant difference ($p<0.05$) in test-retest bending stiffness was found for all directions of movement.

2. Measurement of Staple Loading

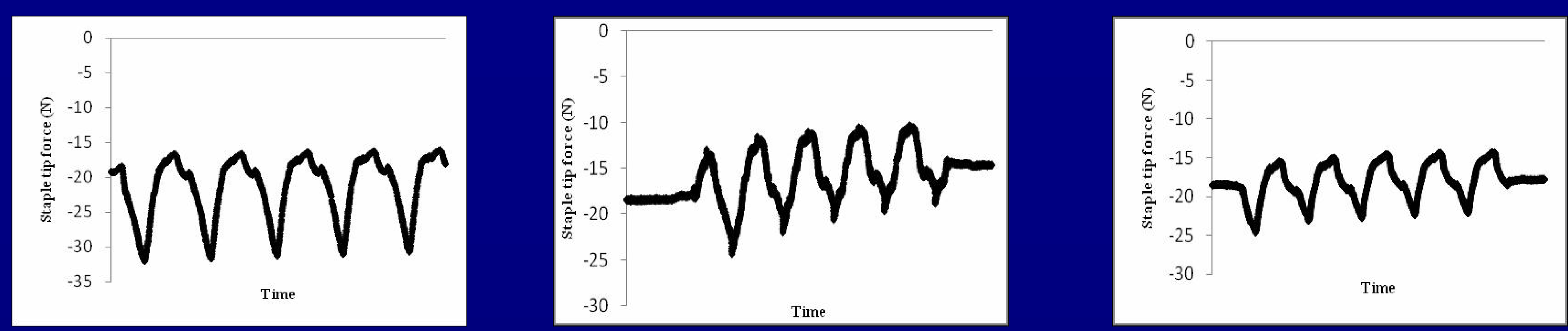
The greatest staple forces were seen in flexion and the least in extension. Representative selections of time-based plots of staple tip loading in each plane of motion are shown in the figures below. Each staple shows a baseline compressive loading on the tips following insertion which gradually, but consistently, decreased across the five cycles of testing for each movement direction.

3. Changes in Vertebral Structure Following Staple Insertion

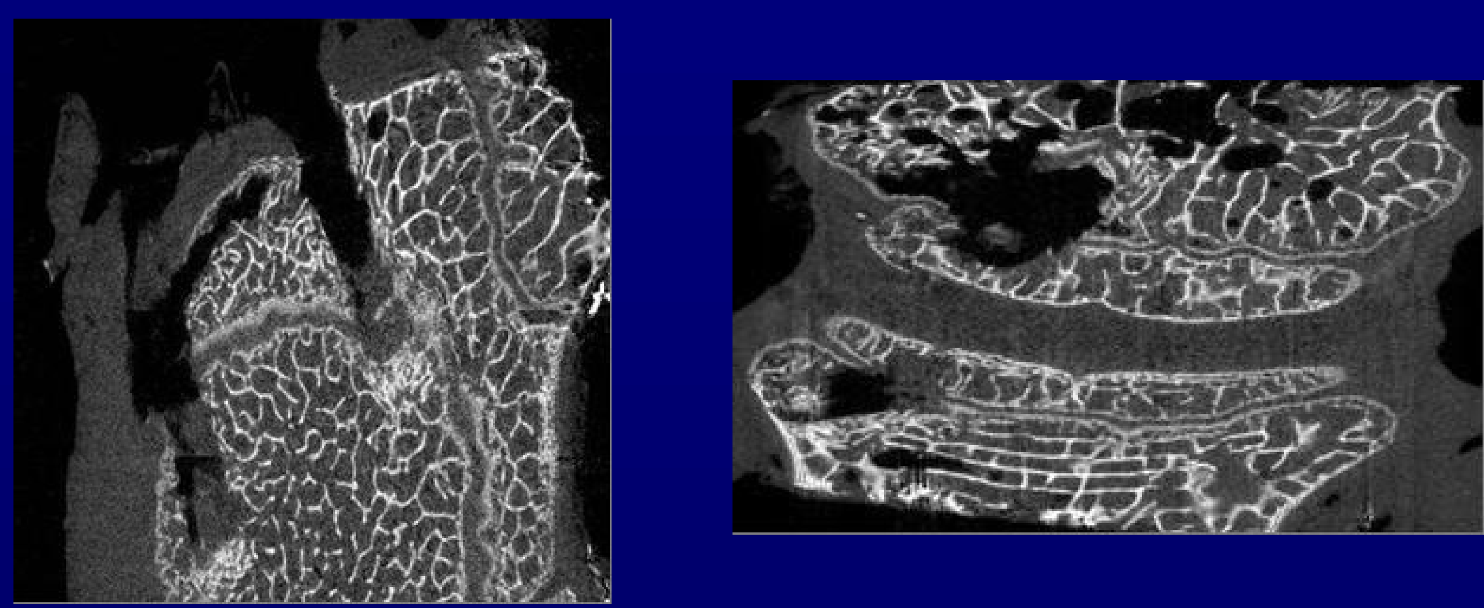
Micro-CT reconstructions of the scanned specimen are shown below. The figures depict significant trabecular bone damage around the staple blades. In addition, unilateral destruction of the growth plate with penetration of the staple tips into the vertebral end-plate has occurred.

Movement	Range of motion	Change in stiffness with staple insertion	P-value
Flexion	2.5°	↓	0.0003
Extension	1.5°	↓	0.04
Lateral bend towards staple	3°	-	0.09
Lateral bend away from staple	3°	↓	0.02
Axial rotation towards staple	4°	-	0.25
Axial rotation away from staple	4°	↓	0.01
Lateral bend toward staple vs. away	3°	-	0.06
Rotation toward staple vs. away	3°	↑ towards	0.04

Range of motion values used for biomechanical testing and results of paired t-tests



Graphs demonstrating staple 'tip' force in flexion-extension, lateral bending, and axial rotation



Micro-CT scans showing significant damage to the vertebral body, growth plate, and end-plate

Discussion

The goal of this project was to describe the anatomical and biomechanical consequences of the insertion of an SMA staple in the thoracic spine. The findings from the biomechanical investigation indicate that staple insertion consistently decreased the bending stiffness of a motion segment. These results could not be attributed to changes in anatomy or tissue properties between tests as each specimen acted as its own control.

Intuitively staple insertion would be expected to increase motion segment stiffness. Indeed, a recent paper by Puttlitz et al found a small but significant decrease in the range of motion in lateral bending and axial rotation using moment controlled testing. [4] The significance of these results were questionable however as several methodological questions made the results difficult to interpret.

An explanation for the finding of decreased motion segment stiffness may be found in the outcomes of the strain gauge testing and micro-CT scan. The strain gauge testing showed that once inserted the staple tips applied a baseline compressive force to the surrounding trabecular bone and vertebral end-plate. This finding would be consistent with the current belief that the clinical effect of the staples is via unilateral compression of the physis. Interestingly however, as each specimen progressed through the five cycles of each test, the baseline load on the staple tips gradually decreased, implying that the force at the staple tip-bone interface was decreasing. We believe that this was likely occurring as a result of structural damage to the trabecular bone and vertebral end-plate by the staple effectively causing 'loosening' of the staple. This hypothesis is further supported by the findings of the micro-CT scan. The pictures depict significant trabecular bone and physeal injury around the staple blades.

Early results to date with SMA staples have been promising in both animal models [1] and a published patient series. [2,3] We propose however, that this effectiveness is not a consequence of unilateral compression of the vertebral physis, but rather that the insertion of an SMA staple causes vertebral hemiepiphysiodesis and subsequent convex growth arrest.

In conclusion, thoracic SMA stapling is a technique which has shown promising early clinical results. Based on our findings it is likely that, contrary to current beliefs, the clinical effect is due to vertebral hemiepiphysiodesis causing convex growth arrest.

References

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